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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of : RONALD A. SCHACHAR  
United States Serial No. : 09/556,143  
Filed : April 21, 2000  
Title : SEGMENTED SCLERAL BAND AND TREATMENT OF  
PRESBYOPIA AND OTHER EYE DISORDERS  
Examiner : David M. Shay  
Art Group Unit : 3739

Assistant Commissioner for Patents  
ATTN: Board of Patent Appeals  
and Interferences  
Washington, D.C. 20231

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APPELLANT'S BRIEF UNDER 37 C.F.R. §1.192

Sir:

This brief is in furtherance of the Notice of Appeal filed in this application on July 5, 2002.

The fees required under 37 C.F.R. §1.17(c), and any required petition for extension of time for filing this appeal brief and fees for any such extension of time, are dealt with in the accompanying transmittal letter.

This brief is transmitted in triplicate (37 C.F.R. §1.192(a)).

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This brief contains these items under the following headings, and in the order set forth below

(37 C.F.R. §1.192(c)):

- I REAL PARTY IN INTEREST
- II RELATED APPEALS AND INTERFERENCES
- III STATUS OF CLAIMS
- IV STATUS OF AMENDMENTS
- V SUMMARY OF INVENTION
- VI ISSUES
- VII GROUPING OF CLAIMS
- VIII ARGUMENTS
  - A. ARGUMENTS - REJECTIONS UNDER 35 U.S.C. § 132
  - B. ARGUMENTS - REJECTIONS UNDER 37 C.F.R. § 1.142
  - C. ARGUMENTS - REJECTIONS UNDER 35 U.S.C. § 102(b)
- IX APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

The final page of this brief before the beginning of the Appendix of Claims bears the attorney's signature.

I REAL PARTY IN INTEREST (37 C.F.R. §1.192(c)(1))

The real party in interest in this appeal is RAS Holding Corporation.

II RELATED APPEALS AND INTERFERENCES (37 C.F.R. §1.192(c)(2))

With respect to other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal, there are no such appeals or interferences.

III STATUS OF CLAIMS (37 C.F.R. §1.192(c)(3))

The status of the claims in this application are:

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

There are sixteen (16) claims in the application (Claims 31-46).

B. STATUS OF ALL THE CLAIMS

1. Claims previously canceled: Claims 1-30.
2. Claims withdrawn from consideration but not canceled: Claims 45-46.
3. Claims pending: Claims 31-44.
4. Claims allowed: None.
5. Claims rejected: Claim 31-44.

C. CLAIMS ON APPEAL

The claims on appeal are 31-46.

IV STATUS OF AMENDMENTS (37 C.F.R. §1.192(c)(4))

In response to the Office Action dated August 13, 2001, the Appellant filed an Amendment on December 13, 2001 (received by the PTO on December 26, 2001). In the December 13, 2001 Amendment the Appellant filed a substitute specification, cancelled Claim 1, amended Claim 31, and added new Claims 45-46. In the Office Action dated April 5, 2002, the Examiner entered the December 13, 2001 Amendment and the substitute specification. The Examiner objected to the Amendment under 35 U.S.C. § 132 for allegedly adding new matter. The Examiner also asserted that Claims 45-46 were directed to an invention that is independent or distinct from the invention originally claimed and therefore withdrew Claims 45-46 from consideration as being directed to a non-elected invention. The Examiner rejected Claims 31-44 under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 4,391,275 to *Fankhauser et al.* (hereafter "*Fankhauser*").

V SUMMARY OF INVENTION (37 C.F.R. §1.192(c)(5))

The present invention relates to the treatment of presbyopia and other eye disorders. Presbyopia is the universal decrease in the amplitude of accommodation of the eyes that is typically observed in individuals over forty years of age. In an individual who has normal vision, the ability to focus on near objects is gradually lost, and the individual then needs glasses for tasks requiring near vision, such as reading.

In the present invention presbyopia is treated by increasing the amplitude of accommodation of the eye by increasing the effective working distance of the ciliary muscle in the presbyopic eye. The effective working distance of the ciliary muscle is increased by expanding the sclera in the region of the ciliary body. This expansion may be accomplished by weakening the sclera of the eye using laser irradiation.

The present invention comprises an apparatus and method for increasing the accommodation of an eye. One advantageous embodiment of the method of the present invention comprises a step of weakening the sclera of the eye through laser irradiation in the region of the ciliary body of the eye to thereby increase the effective working distance of the ciliary muscle. One advantageous embodiment of the apparatus of the present invention comprises a laser that is operable to provide laser irradiation to weaken the sclera of the eye in the region of the ciliary body of the eye to thereby increase the effective working distance of the ciliary muscle.

VI ISSUES (37 C.F.R. §1.192(c)(6))

- A. Whether Appellant's Amendment dated December 13, 2001 added new matter to the patent application.
- B. Whether the Examiner erred in withdrawing Claims 45-46 from consideration as being directed to a non-elected invention.
- C. Whether the Examiner erred in finally rejecting Claims 31-44 under 35 U.S.C. § 102(b) as being anticipated by *Fankhauser*.

VII GROUPING OF CLAIMS (37 C.F.R. §1.192(c)(7))

The Appellant does not make a statement under 37 C.F.R. §1.192(c)(7) regarding the grouping of claims.

VIII ARGUMENTS

A. ARGUMENTS - Rejections under 35 U.S.C. §132 (37 C.F.R. §1.192(c)(8)(v)):

35 U.S.C. §132(a) provides, in pertinent part, that "No amendment shall introduce new matter into the disclosure of the invention." The Examiner objected to the Appellant's Amendment dated December 13, 2002 for allegedly adding new matter. Specifically, the Examiner asserted that "The added material which is not supported by the original disclosure is as follows: the description of figures 10, 11; the disclosure running from line 21 on page 22 through the end of page 25 of substitute specification; and newly submitted figures 10 and 11. Applicant is required to cancel the new matter in the reply to this Office Action." (Page 2, Office Action dated April 5, 2002).

**The Allegedly New Matter Was Present in the Original Patent Application by Incorporation by Reference from United States Patent No. 5,354,331.**

The allegedly new matter was present in the original patent application by the incorporation by reference of United States Patent No. 5,354,331 to *Schachar* dated October 11, 1994. (Page 9, Lines 3-5 of Original Specification) (Page 10, Lines 11-13 of Substitute Specification). The present patent application is a continuation of co-pending United States Patent Application Serial No. 09/032,830 filed on March 2, 1998 (the "'830 Application"). The '830 Application is a continuation-in-part of then co-pending United States Patent Application Serial No. 08/462,649 filed June 5, 1995, now United States Patent No. 5,722,952 (the "'649 Application"). The '649

Application was a co-pending divisional of United States Patent Application Serial No. 08/139,756, filed, October 22, 1993, now U.S. Patent No. 5,489,299 (the "'756 Application"). The '756 Application was a co-pending divisional of United States Patent Application Serial No. 07/913,486, filed on July 15, 1992, now United States Patent No. 5,354,331 (the "'486 Application"). The '830 Application also incorporated by reference the '486 Application, now United States Patent No. 5,354,331, into the body of the '830 Application.

The Appellant respectfully asserts that Figure 10 and Figure 11 clarify the original disclosure but do not add new matter. The matter disclosed in Figure 10 and Figure 11 is supported by the material incorporated by reference from United States Patent No. 5,354,331 to *Schachar*. In particular, the allegedly new matter (i.e., description of figures 10, 11; the disclosure running from line 21 on page 22 through the end of page 25 of substitute specification; and newly submitted figures 10 and 11) is supported by the text of United States Patent No. 5,354,331 to *Schachar* from Column 7, Line 43 through Column 8, Line 45. This portion of United States Patent No. 5,354,331 clearly describes the concept of using laser radiation to weaken the sclera of the eye in the region overlying the ciliary body in order to increase the effective working distance of the ciliary muscle of the eye.

The Appellant respectfully submits that no new matter has been added to the patent application by the Amendment of December 13, 2001. The Appellant therefore also respectfully submits that the Amendment of December 13, 2001 is not objectionable under 35 U.S.C. §132. The Appellant respectfully requests that the Examiner's requirement to cancel the allegedly new matter be withdrawn.

B. ARGUMENTS - Rejections under 37 C.F.R. § 1.142 (37 C.F.R. §1.192(c)(8)(v)):

37 U.S.C. §1.142 provides that:

(a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.

(b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.

In the Office Action dated April 5, 2002 the Examiner characterized Claims 45-46 as being directed to an invention that is independent or distinct from the invention originally claimed. The Examiner withdrew Claims 45-46 from consideration as being directed to a non-elected invention (Page 2, Office Action dated April 5, 2002).

The Applicant respectfully traverses the Examiner's characterization of Claims 45-46. When one compares the subject matter of Claims 45-46 with the subject matter of Claims 31-44 it is clear that Claims 45-46 are not directed to an invention that is "independent or distinct" from the invention claimed in Claims 31-44. Both sets of claims (i.e., Claims 31-44 and Claims 45-46) are directed to increasing the effective working distance of the ciliary muscle of the eye by using laser radiation to weaken the sclera of the eye in the region of the ciliary body.

The Examiner stated that Claims 45-46 were directed to an invention that is independent or distinct from the invention originally claimed "for the following reasons: the apparatus could be used for a substantially different method, such as transmyocardial revascularization." (Page 2, Office



Action of April 5, 2002) (Emphasis added).

Claims 45-46 are directed to a method and not to an apparatus. There is no apparatus claimed in Claim 45 or in Claim 46. There is no apparatus that could be used for "a substantially different method, such as transmyocardial revascularization." The Appellant respectfully submits that the method claimed in Claims 45-46 can not be used for "a substantially different method, such as transmyocardial revascularization." Claims 45-46 are therefore not directed to an invention that is "independent or distinct" from the invention claimed in Claims 31-44.

The Appellant respectfully requests reconsideration of the Examiner's restriction requirement for Claims 45-46. The Appellant respectfully petitions for a review of the restriction requirement and respectfully requests that the restriction requirement for Claims 45-46 be withdrawn.

C. ARGUMENTS - Rejections under 35 U.S.C. § 102(b) (37 C.F.R. § 1.192(c)(8)(iii)):

In the Office Action of January 28, 2002 the Examiner rejected Claims 31-44 under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 4,391,275 to *Fankhauser*. Section 102, in pertinent part, provides that a "person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States." It is axiomatic that anticipation of a claim under § 102 can be found only if the prior art reference discloses every element of the claim. *See, In re King*, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986) (citing with approval, *Lindemann Maschinenfabrik v. American Hoist and Derrick*, 221 U.S.P.Q. 481, 485 (Fed.Cir. 1984)).

Independent Claim 31 and independent Claim 40 read as follows:

31. A laser operable to weaken the sclera of an eye in the region of the ciliary body with laser irradiation to thereby increase the effective working distance of the ciliary muscle of the eye. (Emphasis added).

40. A method of operating a laser to treat one of presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension, said method comprising the step of irradiating the sclera of the eye in the region of the ciliary body to thereby weaken the sclera of the eye and increase the effective working distance of the ciliary muscle of the eye. (Emphasis added).

A determination of anticipation, with respect to Claim 31 or with respect to Claim 40, requires that each feature claimed therein be described in *Fankhauser* in sufficient detail to enable one of ordinary skill in the art to make and practice the claimed invention. Appellants respectfully assert that the above emphasized limitations of Claim 31 and Claim 40 are not disclosed, suggested or even hinted at in the *Fankhauser* reference. In particular, Claim 31 and Claim 40 each recite the limitation of “weakening the sclera of the eye with laser irradiation to increase the effective working distance of the ciliary muscle of the eye.” This limitation is not disclosed, suggested, or even hinted at in the *Fankhauser* reference.

*Fankhauser* discloses a method that uses laser radiation to perforate the tissues of an eyeball in order to reduce an increased level of intra-ocular pressure in the eye due to glaucoma. There is nothing in the *Fankhauser* reference that discloses, suggests or even hints at the invention disclosed and claimed by the Appellant. Simply stated, Claim 31 and Claim 40 are not anticipated by the *Fankhauser* reference. The Appellant respectfully submits that Claim 31 and Claim 40 are

patentable.

As between Claim 40 and the *Fankhauser* reference, the Appellant submits that independent Claim 45 and independent Claim 46 contain limitations analogous to those found in Claim 40. For the reasons given above, the Appellant respectfully asserts that Claim 45 and Claim 46 are also patentable over the *Fankhauser* reference.

Appellant notes that Claims 32-39 depend from Claim 31 and contain all of the unique and novel limitations contained in Claim 31. This being the case, Claims 32-39 are also patentable over the *Fankhauser* reference. Also, Claims 41-44 depend from Claim 40 and contain all of the unique and novel limitations contained in Claim 40. This being the case, Claims 41-44 are patentable over the *Fankhauser* reference.

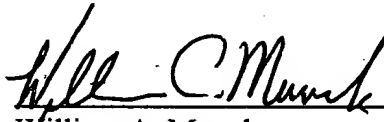
SUMMARY

For the reasons given above, the Appellant respectfully requests reconsideration and allowance of the claims and that this patent application be passed to issue.

Respectfully submitted,

DAVIS MUNCK, P.C.

Date: Sept. 5, 2002

  
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IX APPENDIX OF CLAIMS INVOLVED IN THE APPEAL (37 C.F.R. §1.192(c)(9))

The text of each claim involved in the appeal is as follows:

1. through 30. (Cancelled)

31. A laser operable to weaken the sclera of an eye in the region of the ciliary body with laser irradiation to thereby increase the effective working distance of the ciliary muscle of the eye.

32. The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by abrading the sclera with laser irradiation.

33. The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by ablating the sclera with laser irradiation.

34. The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by incising the sclera with laser irradiation.

35. The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by incising the sclera at select angles with laser irradiation.

36. The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by decomposing partially collagen fibers in the sclera.

37. The laser set forth in Claim 31 wherein said laser is one of a carbon dioxide laser, a helium-neon laser, a helium-cadmium laser, an argon ion laser, a krypton ion laser, a xenon laser, a nitrous oxide laser, iodine laser, a holmium doped yttrium-aluminum garnet laser, an excimer laser, a chemical laser, a harmonically oscillated laser, a dye laser, a nitrogen laser, a neodymium laser, an erbium laser, a ruby laser, a titanium-sapphire laser and a diode laser.

38. The laser set forth in Claim 31 wherein said laser uses one of ionizing radiation and non-ionizing radiation to weaken the sclera of an eye in the region of the ciliary body, thereby increasing the effective working distance of the ciliary muscle of the eye.

39. The laser set forth in Claim 31 operable to increase the amplitude of accommodation of the eye.

40. A method of operating a laser to treat one of presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension, said method comprising the step of irradiating the sclera of an eye in the region of the ciliary body to thereby weaken the sclera of the eye and increase the effective working distance of the ciliary muscle of the eye.

41. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of abrading the sclera with laser irradiation.

42. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of ablating the sclera with laser irradiation.

43. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of incising the sclera with laser irradiation.

44. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of decomposing partially collagen fibers in the sclera.

45. A method for increasing the amplitude of accommodation of an eye, the eye having a crystalline lens, a ciliary muscle and a sclera, said method comprising the step of weakening the sclera through laser irradiation in the region of the ciliary body of the eye thereby increasing the effective working distance of the ciliary muscle.

46. A method for increasing the amplitude of accommodation an eye, the eye having a crystalline lens, a ciliary muscle and a sclera, said method comprising the step of weakening the sclera through one of incising and ablating the sclera in the region of the ciliary body of the eye thereby increasing the effective working distance of the ciliary muscle.